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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/079,416	02/22/2002	Oliver Yoa-Pu Hu	39297-174170	8467

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EXAMINER	
KIM, VICKIE Y	
ART UNIT	**PAPER NUMBER**
1618	

DATE MAILED: 07/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/079,416	YOA-PU HU ET AL	
	Examiner	Art Unit	
	Vickie Kim	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *10-16,33-44 and 46-51* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *44 and 48-51* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *10-16,33-43,46 and 47* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election acknowledged

Applicants' election of species, terpineol, is acknowledged. Applicants made the election without traverse. Therefore, the election requirement is maintained, and made FINAL. The claims which are readable on the specie of terpineol are claims 44, 48-51.

Claims 10-16, 33-44, and 46-51 are now pending.

The claims 44, 48-51 have been examined only to the extent that they read on use of the elected species in the claimed method.

All remaining(or portions thereof) claims not drawn to the elected species are withdrawn from further consideration as being non-elected. The following rejections are made.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 44 and 48-51 are rejected under 35 U.S.C. 102(b) as being anticipated by Eini et al(US5227163).

Independent claim 44 is drawn to a composition comprising terpineol(as a dermal CYP1A inhibitor) and a carrier. Claim 51 requires terpineol present in the amount of about 10% by weight.

Claims 49-50 additionally requires a dermatological drug(e.g. terpineol, retinoic acid , etc)

Eini et al(US'163, hereafter) teaches a composition comprising terpenoids such as terpeneols(=terpineol) in a concentration of between 0.01-50%,preferably 0.01-10%, by weight and a pharmaceutically and/or cosmetically effective carrier, see abstract. It is noted that terpineol is a CYP1A inhibitor(self evidenced by claims 44) and thus claims are inherently met. There are 16 terpeneols available and a mixture of different terpeneols can be used to make the patented composition, see claims 1 and 7.

Claim 48 is properly included in this rejection because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

It is noted again that the invention is drawn to a composition. The recitation(e.g. co-administration with other dermatological drug) in preamble is considered to be a description of intended use. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference

as compared to the prior art. See *In re Casey*, 370 F.2d 576, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 312 F.2d 937, 939, 136 USPQ 458, 459 (CCPA 1963). In response to applicant's arguments, the recitation(i.e. wherein said pharmaceutical composition is applied to skin together with a dermatological drug such as retinoic acid or retinoid) has not been given patentable weight .

All the critical elements required by the instant claims are well taught and all the claims 44, 48-49 and 51 are anticipated by the cited reference.

3. Claims 44 and 48-51 are rejected under 35 U.S.C. 102(b) as being anticipated by, or alternatively as being obvious over Nonomura et al(US6020288).

US'288 teaches a composition for inducing cytochromoe P450 monooxygenase, comprising a combination of terpenoids and retinoid, see abstract and claims, especially claim 32. It is well known in the art that terpineol is terpinoids, a specie classified under terpinoids and thus, the claims are met by the cited reference. The examiner's allegation is evidenced by US'5227163(Eini, cited immediately above), see abstract.

At any event(in case of that applicant does not agree on the examiner's allegation), the patent(US288) , as evidenced by claim 32, utilizes a mixture of retinoid, terpenoid and alcohol. As known in the art, terpineol is terpinoid-alcohol(see US'163, abstract), and thus, a convenient form of terpinoids and alcohols mixture that is used to make up the patented composition. Therefore, one would have motivated to use terpeniol(terpenoid-alcohol) to increase the industrial applicability(by adding convenience and reducing the cost).

All the critical elements required by the instant claims are well taught in the cited reference and thus, the claimed subject matter is not patentably distinct over the prior art of the record.

4. Claims 44 and 48-51 are rejected under 35 U.S.C. 102(e) as being anticipated by, or alternatively as being obvious over Bortlik et al(US2002/0107292 A1).

US'292(Bortlik et al) teaches a composition for inducing cytochromoe P450 monooxygenase, comprising a combination of terpenoids and retinoid, see abstract and claim 7. For the very same reason set forth immediately above(Nonomura et al, US6020288), the claimed subject matter is not patentably distinct over the prior art of the record.

Conclusion

5. No claim is allowed. Having carefully reviewed applicants' Request for Reconsideration, the examiner maintained the rejection in any respect.

6. **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vickie Kim whose telephone number is 571-272-0579. The examiner can normally be reached on Tuesday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Chris Low be reached on 571-272-0953. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

VICKIE KIM
PRIMARY EXAMINER

Vickie Kim
Primary Patent Examiner
July 11, 2005
Art unit 1618